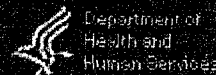


## **Exhibit-4**

**F.D.A.'s guidance for industry, regarding 2004  
FALCPA, published on October 5, 2005**



**U.S. Food and Drug Administration**



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October 5, 2005

## Guidance for Industry

# Questions and Answers Regarding Food Allergens, including the Food Allergen Labeling and Consumer Protection Act of 2004

## Final Guidance

Comments and suggestions regarding this document may be submitted at any time. Submit comments to Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

For questions regarding this document, contact Rhonda R. Kane at the Center for Food Safety and Applied Nutrition (CFSAN) at 301-436-2371 or email [rhonda.kane@fda.hhs.gov](mailto:rhonda.kane@fda.hhs.gov).

*Additional copies are available from:*

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*Center for Food Safety and Applied Nutrition*

*Food and Drug Administration, 5100 Paint Branch Parkway*

*College Park, MD 20740*

*<http://www.cfsan.fda.gov/guidance.html>*

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Food Safety and Applied Nutrition (CFSAN)  
October 5, 2005**

## Guidance for Industry

# Questions and Answers Regarding Food Allergens, including the Food Allergen

# Labeling and Consumer Protection Act of 2004

This guidance represents the current thinking of the Food and Drug Administration on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations. If you wish to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this document.

## I. Introduction

As originally enacted in 1938, section 403(i) of the Federal Food, Drug, and Cosmetic Act required that the label of a food that is fabricated from two or more ingredients declare each ingredient by its common or usual name (except that spices, flavorings, and colors could be declared as a class.) Although ingredient declarations complying with section 403(i) provide some information to food allergic consumers, in some cases, the common or usual name of an ingredient may be unfamiliar to consumers and many consumers do not recognize that certain ingredients contain or are derived from a food allergen. This situation led, at least in part, to the enactment of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Pub. L. 108-282).

This is the first edition of a guidance document that contains questions and answers relating to food allergens, including questions and answers about the Food Allergen Labeling and Consumer Protection Act. FDA expects to issue subsequent editions of this guidance document by adding new questions and answers to the guidance; new questions and answers will be identified by the date that they are added to the guidance.

FDA's guidance documents, including this document, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

## II. Questions and Answers

### 1. What is the Food Allergen Labeling and Consumer Protection Act of 2004?

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) (Public Law 108-282) was enacted in August 2004, and addresses, among other issues, the labeling of foods that contain certain food allergens.

### 2. When do the labeling requirements of the Food Allergen Labeling and Consumer

**Protection Act (FALCPA) become effective for packaged foods sold in the United States?**

All packaged foods regulated under the Federal Food, Drug, and Cosmetic Act (FFD&C Act) that are labeled on or after January 1, 2006, must comply with FALCPA's food allergen labeling requirements.

3. **Must products with labels that do not comply with FALCPA be removed from the market place once the new labeling law is effective?**

No. FALCPA does not require any action with respect to products labeled before January 1, 2006.

4. **What is a "major food allergen?"**

Under FALCPA, a "major food allergen" is an ingredient that is one of the following five foods or from one of the following three food groups or is an ingredient that contains protein derived from one of the following:

- o milk
- o egg
- o fish
- o Crustacean shellfish
- o tree nuts
- o wheat
- o peanuts
- o soybeans

5. **Does FALCPA provide any specific direction for declaring the presence of ingredients from the three food groups that are designated as "major food allergens (i.e., tree nuts, fish, and Crustacean shellfish?")**

Yes. FALCPA requires that in the case of tree nuts, the specific type of nut must be declared (e.g., almonds, pecans, or walnuts). The species must be declared for fish (e.g., bass, flounder, or cod) and Crustacean shellfish (crab, lobster, or shrimp).

6. **Are there food allergens other than those directly addressed by FALCPA?**

Congress designated eight foods or food groups as "major food allergens." These foods or food groups account for 90 percent of all food allergies. Although there are other foods to which sensitive individuals may react, the labels of packaged foods containing these other allergens are not required to be in compliance with FALCPA.

7. **What types of foods are covered by the FALCPA labeling requirements?**

FALCPA's requirements apply to all packaged foods sold in the U.S. that are regulated under the Federal Food, Drug, & Cosmetic Act, including both domestically manufactured and imported foods. FDA regulates all foods except meat products, poultry

products, and egg products.

**8. Are fresh fruits and vegetables in their natural state subject to FALCPA's requirements?**

No. Raw agricultural commodities such as fresh fruits and vegetables in their natural state are not affected by FALCPA.

**9. Does FALCPA affect the labeling of packaged meat, poultry, and egg products regulated by the U.S. Department of Agriculture (USDA)?**

FALCPA's requirements apply only to those foods regulated by the Food and Drug Administration under the FFD&C Act. We recommend that producers of meat products, poultry products, and egg products regulated by USDA contact the appropriate USDA agency regarding the labeling of such products.

**10. May the terms "soybean," "soy," and "soya" be considered synonyms for the term "soybeans" for the purpose of satisfying the FALCPA labeling requirements?**

Yes. "Soybean," "soy," and "soya" are reasonable synonyms for the common or usual name "soybeans," and any one of these terms may be used to identify the food source of the major food allergen "soybeans."

**11. When is it appropriate to use the term "soybeans" versus a synonym in food labeling?**

Packaged foods that are made using soybeans as an ingredient or as a component of a multi-component ingredient (e.g., soy sauce or tofu) should continue to use the word "soybeans" as the appropriate common or usual name for this ingredient to identify properly the ingredient (e.g., "soy sauce (water, wheat, soybeans, salt)").

**12. May the singular term "peanut" be substituted for the plural term "peanuts," and may the singular terms (e.g., almond, pecan, or walnut) be used to describe the different types of "tree nuts" (e.g., almonds, pecans, or walnuts) to satisfy the labeling requirements of FALCPA?**

Yes. FDA believes that "peanut" is an acceptable substitute for "peanuts" and that the names of the different types of tree nuts may be expressed in either the singular or plural form for the purpose of satisfying the FALCPA labeling requirements.

**13. May a "Contains" statement on a food label provided in accordance with FALCPA list only the names of the food sources of the major food allergens that are not already identified in the ingredient list for a packaged food?**

No. If a "Contains" statement is used on a food label, the statement must include the names of the food sources of all major food allergens used as ingredients in the packaged food. For example, if "sodium caseinate," "whey," "egg yolks," and "natural peanut flavor" are declared in a product's ingredients list, any "Contains" statement appearing on the label immediately after or adjacent to that statement is required to identify all three

sources of the major food allergens present (e.g., "Contains milk, egg, peanuts") in the same type (i.e., print or font) size as that used for the ingredient list..

**14. Is there more than one way to word a "Contains" statement used to declare the major food allergens in a packaged food?**

Yes. The wording for a "Contains" statement may be limited to just stating the word "Contains" followed by the names of the food sources of all major food allergens that either are or are contained in ingredients used to make the packaged product. Alternatively, additional wording may be used for a "Contains" statement to more accurately describe the presence of any major food allergens, provided that the following three conditions are met:

- a. The word "Contains" with a capital "C" must be the first word used to begin a "Contains" statement. (The use of bolded text and punctuation within a "Contains" statement is optional.)
- b. The names of the food sources of the major food allergens declared on the food label must be the same as those specified in the FALCPA, except that the names of food sources may be expressed using singular terms versus plural terms (e.g., walnut versus walnuts) and the synonyms "soy" and "soya" may be substituted for the food source name "soybeans."
- c. If included on a food label, the "Contains" statement must identify the names of the food sources for all major food allergens that either are in the food or are contained in ingredients of the food.

**15. Is there a penalty for non-compliance with FALCPA?**

Yes. A company and its management may be subject to civil sanctions, criminal penalties, or both under the Federal Food, Drug, and Cosmetic Act if one of its packaged food products does not comply with the FALCPA labeling requirements. FDA may also request seizure of food products where the label of the product does not conform to FALCPA's requirements. In addition, FDA is likely to request that a food product containing an undeclared allergen be recalled by the manufacturer or distributor.

**16. Does FALCPA require food manufacturers to label their products with advisory statements, such as "may contain [allergen]" or "processed in a facility that also processes [allergen]"?**

No. FALCPA does not address the use of advisory labeling, including statements describing the potential presence of unintentional ingredients in food products resulting from the food manufacturing process. FALCPA does require FDA to submit a report to Congress, a part of which assesses the use of, and consumer preferences about, advisory labeling. In earlier guidance, FDA advised that advisory labeling such as "may contain [allergen]" should not be used as a substitute for adherence to current Good Manufacturing Practices (cGMPs). In addition, any advisory statement such as "may contain [allergen]" must be truthful and not misleading.

**17. Does FALCPA require FDA to set so-called thresholds for any food allergen?**

FALCPA does not require FDA to establish a threshold level for any food allergen. It is not unlikely, however, that FDA will at some point need to consider a threshold level for one or more food allergens in the context of reviewing a petition or a notification submitted to request that an ingredient be exempt from FALCPA's labeling requirements.

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